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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Government-Owned Inventions; Availability for Licensing**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Pitts, Ph.D., 240-669-5299; elizabeth.pitts@nih.gov. Licensing information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

**SUPPLEMENTARY INFORMATION:** Technology description follows.

**Protein Nanoparticle-Based Vaccine for Influenza Virus**

**Description of Technology:**

There is a great need for a broadly protective, "universal" influenza virus vaccine. Most influenza vaccines target the head of the influenza surface glycoprotein hemagglutinin (HA). However, this region of the HA protein undergoes fast antigenic drift. The current strategy to address this issue is to reformulate influenza vaccines annually against dominant circulating strains, but this leads to variable protective efficacy against annual epidemic strains and will not provide protection against novel influenza viruses with pandemic potential. A "universal" influenza vaccine could improve seasonal vaccination and provide pandemic preparedness.

Broadly neutralizing antibodies with heterosubtypic binding have been discovered. However, commercial development of vaccines that produce broadly neutralizing antibodies has so far been unsuccessful. Researchers at NIAID used structure-guided techniques to identify and develop nanoparticles that express a conserved peptide from the HA stem, a preferred antigen for influenza vaccine development as it evolves slower than the HA head. The nanoparticles of this invention elicit antibodies to the HA stem, confer protection in mouse challenge models, are cross-reactive to heterosubtypic HA subtypes, and are heat stable. Additionally, the protein platform of the nanoparticles can be expressed for group 1 and group 2 influenza HA (H1 to H16), which allows mixing of antigens. This vaccine technology has great potential to provide protection against both annual influenza outbreaks and pandemic-potential influenza viruses.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. § 209 and 37 CFR Part 404.

**Potential Commercial Applications:**

- Vaccines against influenza virus
- Universal influenza virus vaccine

**Competitive Advantages:**

- Broad/universal protection against both seasonal and pandemic-potential influenza viruses
- Nanoparticles allow mixing of antigens
- Incorporates epitopes from group 1 and groups 2 influenza viruses
- Stability of particle and immunogenicity after high temperature exposure

**Development Stage:**

- In vivo data assessment (animal)

**Inventors:** Audray K. Harris (NIAID) and Dustin McCraw (NIAID)

**Intellectual Property:** HHS Reference No. E-005-2017 – U.S. Provisional Application No. 62/540,474, filed August 2, 2017; PCT Application No. PCT/US2018/045032, filed August 2, 2018; United States Application No. 16/635,240, filed January 30, 2020 (pending); European Application No. 18756111.3, filed August 2, 2018 (pending); Chinese Application No. 201880063622.5, filed August 2, 2018 (pending); and Indian Application No. 202017008138, August 2, 2018 (pending).

**Licensing Contact:** To license this technology, please contact Elizabeth Pitts, Ph.D., 240-669-5299; elizabeth.pitts@nih.gov.

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Surekha Vathyam,

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